UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/526,765 | 03/07/2005 | Odile Letourneur | 122802 | 5831 |

25944 7590 10/10/2007

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

| EXAMINER | |
|---|---|
| PENG, BO | |
| ART UNIT | PAPER NUMBER |
| 1648 | |
| MAIL DATE | DELIVERY MODE |
| 10/10/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/526,765 | LETOURNEUR, ODILE | |
| | Examiner | Art Unit | |
| | Bo Peng | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/2005 and 6/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Restriction election*

1. The Office acknowledges the receipt of Applicant's election of species, filed on July 20, 2007. Applicant provisionally elects SEQ ID NO: 51 as a species of a recombinant DNA recited in Claim 1, with traverse. Applicant indicates that SEQ ID NO: 51 comprises SEQ ID NOs: 21, 27, 29, 31, 35, 37 and 39.

2. Applicant's traverse is on the ground that the office action failed to make a *prima facie* case of lack of unity as failed to apply any prior art. Therefore, the election of species requirement is improper. Moreover, the generic claims are not so broad as to place an undue burden on the Patent Office to search and examine the full scope of the claims. Rather, search and examination of the entire application could be conducted without undue burden on the Examiner.

3. Applicant's arguments are fully considered, but found not persuasive for the following reasons: first, because no prior art was applied, no restriction was required. However, as indicated in the office action, requirement of species election was proper because different SEQ ID Nos lack the same or corresponding special technical features according to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions. Moreover, the 23 SEQ ID Nos in the instant claims result in hundreds of combinations, simultaneous search and examination of all of them would constitute a serious burden to the Office. Finally, in order to examine the entire application efficiently, avoiding delay and expense to Applicants, claims are searched and examined using an approach of examining the Applicant's preferred species first, and then genus. Thus, the full scope of claims is search and examined (see

MPEP 803.02). The requirement of species election is still deemed proper and is therefore made FINAL.

4. Accordingly, Claims 1-13 are pending and are examined to the extent that they read upon the elected species SEQ ID No: 51, which comprises SEQ ID NOs: 21, 27, 29, 31, 35, 37 and 39.

***Specification***

5. The use of trademarks has been noted in this application, e.g. Vidas® throughout the text. Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. Sequence identifier should be indicated as SEQ ID No: 1, etc., not SEQ ID No. $^{0}1$, etc. Correction is required.

***Information Disclosure Statement***

7. The information disclosure statement submitted on June 8, 2005, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office action.

8. The information disclosure statement submitted on June 15, 200 has not been considered by the examiner because IDS form 1449 submitted on June 15, 2005 is for Application No. 10/086, 806, not for the instant Application.

***Claim objections***

9. Sequence identifiers for the claims should be indicated as SEQ ID No: 1, etc., not SEQ ID No. $^{0}$1, etc. Correction is required.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallarda J. *et al.* (WO 95/33206, cited in IDS) and Han (1998, Biochemistry and Mol. Biology International, 46(3):607-617, cited in IDS), both in view of inNovations (Newsletters of Novagen, Inc. No.11 (June 2000): p. 1, 12 and 13).

12. **Claims 1-6** are directed to a recombinant DNA encoding a chimeric recombinant protein, comprising at least two first nucleotide fragments each encoding an epitope region of the HIV-1 virus group M or group O or of the HIV-2 virus, at least a second nucleotide fragment encoding a linking region, at least a third nucleotide fragment encoding an attaching region, characterized in that each first nucleotide fragment encodes at least one immunodominant region of the gp120 glycoprotein of HIV-1, of the gp41 glycoprotein of HIV-1 group M, of the gp41 glycoprotein of HIV-1 group O or of the gp36 glycoprotein of HIV-2, wherein said first nucleotide fragment has

as its sequence any one of the sequences SEQ ID No:3, SEQ ID No:5, SEQ ID No:7, SEQ ID No:9, SEQ ID No:27, SEQ ID No:29 or SEQ ID No:31, wherein said second nucleotide fragment comprises at least one cleavage site, wherein said second nucleotide fragment has as its sequence at least any one of the following sequences, taken alone or in combination, SEQ ID Nos:11, 13, 15, 17, 9, 20, 33, 35, 37, 39, 41, 43, 45, or 47, wherein said third nucleotide fragment encoding an attaching region is included in said second nucleotide fragment encoding a linking region, wherein said third nucleotide fragment has as its sequence any one of the sequences SEQ ID Nos: 21, 23, 25, 33, 35, 37 or 39. **Claims 7-13** are directed to a chimeric recombinant protein encoded by a recombinant DNA as claimed in Claim 1, comprising at least two epitope regions of the HIV-1 virus group M or group O or the HIV-2 virus, at least one linking region, at least one attaching region, wherein said linking region is a peptide comprising at least one glycine and/or at least one serine, wherein said linking region has as its sequence any one of the sequences SEQ ID Nos: 12, 14, 16, 18, 34, 36, 38, 40, 42, 44, 46 or 48, wherein said attaching region is a region rich in histidines and derivatives thereof, such as a region containing a density of histidines greater than or equal to 25%, and preferably greater than or equal to 33%, wherein said attaching region is a peptide comprising at least one lysine, wherein said attaching region has as its sequence SEQ ID No: 22, 24, 26, 34, 36, 38 or 40. Claim 13 is directed to an expression vector comprising a recombinant DNA as claimed in Claim 1.

13. Applicant provisionally elects species SEQ ID NO: 51 that comprises SEQ ID NOs: 21, 27, 29, 31, 35, 37 and 39. Based on the specification, SEQ ID NO: 51 encodes an attaching region SEQ ID NO: 22, epitope regions SEQ ID NOs: 28, 32 and 30, and linking regions SEQ ID NOs: 40, 36 and 38.

14. Gallarda teaches an assay to simultaneously detect the presence of antibodies of HIV-1 Group M, Group O and/or HIV-2 in a test sample using immunodominant epitopes of HIV-1 and HIV-2. Gallarsa teaches that the analytes are captured on either the same or different solid phases, and the presence of the analytes is determined by detecting a signal generated by using a cocktail of synthetic and recombinant antigen-containing indicator reagents. Gallarda teaches that preferred indicator reagents include peptides homologous to an immunodominant region of HIV-I gp 41 and an immunodominant region of HIV-2 gp 36, wherein the HIV-2 antigens comprising amino acids sequences that are 100% identical to the instant SEQ ID NO: 32 (See Claim 5), wherein the HIV-1 antigens comprising amino acids that are 100% identical to the instant SEQ ID NO: 28 (see Claim 10), and 100% identical to 3-23 a.a. of the instant SEQ ID NO: 30 (Claim 9). Thus, Gallard teaches all the epitopes encoded by elected species SEQ ID NO: 51. Gallarda shows that antigens can efficiently capture HIV antibodies in the sample, so that they simultaneously detect the presence of antibodies of HIV-1 Group M, Group O and/or HIV-2 in a test sample (Examples). Gallard teaches expression vectors encoding peptides containing HIV-1/2 epitopes (p. 42-49).

15. Gallarda does not explicitly teach making a recombinant DNA encoding a chimeric protein of these HIV-1/2 antigens, nor a chimeric protein containing HIV-1/2 antigens.

16. Han teaches a recombinant DNA encoding a chimeric protein of HIV-1 and HIV-2 immunodominant epitopes, and the chimeric protein containing HIV-1 and HIV-2 immunodominant epitopes (p. 607-614). Han teaches that the chimeric protein containing HIV-1/2 epitopes can react with antibodies in HIV positive serum samples, without cross-reaction with HIV negative serum samples (614-616).

17. inNovations teaches a plasmid containing (His)6 gene that is identical to the instant third nucleotide SEQ ID NO:21, which encodes (His)6-tag of the instant attaching region SEQ ID NO:22 (pp.12 and 13). InNovations teaches that (His)6-tag can be used for detecting His-tag preoteins using His.Tag monoclonal antibody (p.12).

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a recombinant DNA encoding a chimeric protein containing HIV-1 and 2 antigens in order to generate fusion proteins for detecting HIV-1 and 2 antibodies as taught by Gallarda and Han. The skilled artisan would have been motivated to do so and have a reasonable expectation of success, given that the HIV-1 and 2 immunodominant epitopes SEQ ID NOs: 28, 32 and 30 can be successfully used for simultaneous detection of HIV-1 and 2, as taught by Gallarda, and also given that a chimeric protein containing immunodominant epitopes can also work well for detecting HIV in a sample, as taught by Han, also given that plasmids containing (His)6-tag are readily commercially available. It is within of ordinary skill in that art to make a recombinant plasmid containing SEQ ID No: 51 by standard molecular techniques. Thus, the invention as a whole was clearly *prima facie* obvious over Gallarda and Han, in view of inNovations.

***Remarks***

19. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP
Bo Peng, Ph.D.

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600